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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,972	03/22/2004	Stephen Donovan	17500CON (BOT)	2337
51957	7590	12/12/2006	EXAMINER	
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,972

Applicant(s)

DONOVAN, STEPHEN

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7, 10-22 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

2. Claims 21-22 define over the prior art of record and therefore are allowed.

Rejections Withdrawn

3. **Double Patenting** Claims 1-7, 10-22 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,921,538 is herein withdrawn in light of the effective terminal disclaimer.

Rejections Maintained/ Response to Arguments

4. Applicant's arguments filed October 4, 2006 have been fully considered but they are not persuasive.
5. **Claim Rejections - 35 USC § 102** The rejection of claims 1-4, 7, 17 and 20 under 35 U.S.C. 102(b) as being anticipated by Micheli et al (1998) is traversed on the grounds that the claims are directed to treating a neuropsychiatric disorder and not a neuromuscular disorder.
6. It is the position of the examiner that claims are directed to “**alleviating a symptom** of a neuropsychiatric disorder”, the symptoms being defined to include:

“[0020] Anxiety disorders may affect between approximately ten to thirty percent of the population, and may be characterized by frequent occurrence of symptoms of fear including

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arousal, restlessness, heightened responsiveness, sweating, racing heart, increased blood pressure, dry mouth, a desire to run or escape, and avoidance behavior. Generalized anxiety persists for several months, and is associated with motor tension (trembling, twitching, muscle aches, restlessness); autonomic hyperactivity (shortness of breath, palpitations, increased heart rate, sweating, cold hands), and vigilance and scanning (feeling on edge, exaggerated startle response, difficult in concentrating).”

The patient disclosed in Micheli et al had two symptoms that were treated with botulinum toxin, specifically motor tension which manifested itself by twitching spasms and hypertension which is associated with increased blood pressure. Therefore, in light of the claims being directed to alleviating symptoms and the symptoms having been defined to include symptoms manifest in the patient of Micheli et al, and the site of administration being that local to the “facial pontine root entry zone (see line two, abstract, Micheli et al)” which is within the claimed pontine region, Micheli et al still anticipates the instantly claimed invention as now claimed.

7. The rejection of claims 1-7, 12-16, 20 under 35 U.S.C. 102(b) as being anticipated by Auchus et al (1995) is traversed on the grounds that “Auchus only discloses botulinum toxin injection into certain neck muscles” and “All claims are limited to administration of a botulinum toxin to particular brain regions.”

8. It is the position of the examiner that Auchus et al alleviated at least one symptom associated with a neuropsychiatric disorder (see title, cervical dystonia in dementia), wherein the disorder is Alzheimer’s disease (see page 393, col. 1, paragraph 2), the neurotoxin being botulinum toxin A (see page 393, col. 1, paragraph 4) and the botulinum toxin was administered

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locally to cervical muscles of the head, a location of the lower brain region to treat dystonia associated with dementia (see title).

Applicant's definition of local administration does not require the injection of botulinum toxin into the brain region, but includes "to the vicinity" of a site:[0074] "Local administration" means direct administration of a pharmaceutical at or to the vicinity of a site on or within an animal body, at which site a biological effect of the pharmaceutical is desired. Local administration excludes systemic routes of administration, such as intravenous or oral administration.

Auchus administered the botulinum toxin "to the vicinity of the lower brain region to treat a symptom of a neuropsychiatric disorder and therefore still anticipates the instantly claimed invention as now claimed.

Double Patenting

9. Claims 1-7, 10-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6620415. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of invention administers botulinum toxin to the lower brain region, to the pontine region and the mesopontine region to alleviate a motor disorder symptom which is a symptom associated with anxiety; the allowed species is narrower than the instantly pending claims which may administer the composition locally or directly into the lower brain region or pontine region, while the allowed species administers the botulinum toxin directly to the lower

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brain region or pontine region. The allowed species anticipates the instantly claimed genus as now claimed.

10. Claims 1-7, 10-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-36 of copending Application No. 10/964,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications administer botulinum toxin to treat a neuropsychiatric disorder and the copending '898 Application administers the botulinum toxin to a specific location, the trigeminal nerve, that is local to the lower brain region and the instantly pending claims are directed to a genus of locations local to the lower brain region. The copending species anticipates the instantly claimed genus of methods of treating a neuropsychiatric disorder and is encompassed by the instantly claimed genus of methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-7, 10-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/421,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications administer botulinum toxin to treat a neuropsychiatric disorder and the copending '504 Application administers the botulinum toxin to a specific intracranial location, that includes the lower brain region and pontine regions of the instantly pending claims. The copending species anticipates the instantly claimed genus of methods of treating a neuropsychiatric disorder and is encompassed by the instantly claimed genus of

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methods. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceedings should be directed to Victor Barlow for Art Unit 1645 whose telephone number is 571-272-0506.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
December 4, 2006



MARK NAVARRO
PRIMARY EXAMINER